REMARKS

Claims 1-40 are pending. By this Amendment, claims 16, 19, 21, 26, 33, and 39 are amended, numerous minor errors in the specification are corrected, and substitute drawings are provided. Claims 1-40 remain pending. No new matter is entered by this amendment.

Amendments to specification

Applicants amend numerous paragraphs to correct minor typographical errors that would have been readily apparent to one of ordinary skill in the art. Applicants direct the Examiner's attention in particular to the amendment of the paragraph beginning on page 20 of the specification as filed. At the end of this paragraph, reference was made incorrectly to U.S. Patent No. 4,503,767. The correct reference is to U.S. Patent No. 4,505,767, which is directed to shape memory alloys as discussed in the present application. Brief inspection of U.S. Patent 4,503,767 shows that it is directed to subject matter not relevant in the present application. Applicants therefore respectfully request that the Examiner enter this amendment.

Amendments to claims

Applicants amend the claims to correct minor typographical errors. The scopes of the amended claims are not altered thereby, and no new matter is entered.

Substitute drawings

Applicants provide substitute drawings to comply with 37 C.F.R. § 1.84. Applicants submit that none of the substitute drawings contains substantive changes. Rather, the substitute drawings illustrate with greater clarity and accuracy certain embodiments and features of the disclosed systems and methods that were already depicted in the drawings as originally filed.

The substitute drawings include no new matter. Support for the substitute drawings can be found throughout the specification, claims, and drawings as originally filed.

The original drawings were prepared by the Attorney for the Applicants to illustrate informally some features and principles of particular embodiments. The substitute sheets are provided to correct artistic inadequacies of the original drawings while retaining each enumerated feature in its proper relative position. No substantive changes have been made. Therefore, Applicants respectfully request entry of the substitute drawings.

CONCLUSION

No new matter has been added by this Preliminary Amendment. Applicants therefore respectfully request its entry. No fee is believed due with the filing of this Preliminary Amendment. However, the Commissioner is authorized to charge/credit any deficiencies/ overpayments to our Deposit Account, No. **06-1448**.

Please direct questions regarding this submission to the undersigned at 617-832-1198 or at the telephone number listed below.

Respectfully submitted,
FOLEY HOAG LLP

Dated: July 15, 2002

M. Sharon Webb, M.D., Ph.D.
Registration No. 47,172
Attorney for Applicants

Customer No. 25,181
Patent Group
FOLEY HOAG LLP
155 Seaport Blvd
Boston, MA 02210-2600
Tel.: (617) 832-1230
Fax: (617) 832-7000

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the specification:

Please replace the paragraph beginning at page 1, line 21, with the following paragraph:

--A number of surgical procedures are well-known in the arts for affixing tissues to each other, thereby repairing their abnormal pathophysiologies. As an example, tissues that have become ~~inordinantly~~inordinately lax or stretched or torn can allow structures or organs to become malpositioned, so that their physiologic functions are altered. In certain body areas, the malposition of a structure due to loss of regional support is referred to as "ptosis," although this term may not be generally used to refer to malposition in certain other body areas, such as the female pelvis. A situation of tissue or organ malposition due to loss of regional support is seen in pelvic conditions such as cystoceles and rectoceles, as well as in frank uterine prolapse or vaginal vault prolapse. Repairing lax, torn or stretched tissues in general may be termed a "pexy." As another example wherein tissues are affixed to each other to repair their abnormal physiologies, a surgeon may attach two tissues to each other in a non-anatomic relationship to repair an organ's abnormal physiology, as is seen in a Nissen fundoplication for esophageal reflux.--

Please replace the paragraph beginning at page 2, line 24, with the following paragraph:

--Laxities in the female pelvic floor provide an example of an anatomic situation where tissue stretch, tearing or relaxation can lead to physiological abnormalities. Defects in this area may be related to past pregnancies and childbearing, or may be related to loss of soft tissue tone

after menopause or with aging. Whatever their etiologies, these defects may result in a variety of urogenital abnormalities, such as cystoceles, rectoceles, vaginal prolapse and genuine stress urinary incontinence. Surgical treatment of this condition may be necessary in up to 11% of the female population; there is presently about a 30% failure rate to such surgery, leading either to further surgery or to alternative treatment with appliances such as vaginal pessaries. Either a vaginal, an open or a laparoscopic approach can be used to perform soft tissue reconstruction in this area. When traditional surgical techniques are used to treat laxities in the female pelvic area, incisions may need to be made in the vaginal mucosa and dissection may need to be carried into the spaces between adjacent organs such as the bladder and rectum, which may lead to blood loss, scarring, denervation, and an unacceptably high failure rate. Laparoscopic procedures directed to this anatomic region have both advantages and disadvantages: advantages include improved visualization of particular areas of the pelvic anatomy, shortened hospitalization, decreased postoperative pain and more rapid recovery; disadvantages include the technical difficulties of the dissection, increased operating time and increased hospital cost due to the length of surgery. (MF Paraiso, T Falcone and MD Walters, "Laparoscopic surgery for genuine stress ~~incontinceence~~incontinence," Int. Urogynecol J. 10:237-247, 1999)--

Please replace the paragraph beginning at page 12, line 4, with the following paragraph:

--While affixation devices according to these systems and methods are not adapted for the repair of traumatic or surgical wounds, they may take advantage of wound healing processes stimulated by their presence. For example, an affixation device may be made of biocompatible, biodegradable materials whose local presence stimulates tissue ingrowth and wound healing

processes, thereby forming scar tissue. As another example, an affixation device may be coated with materials that would encourage tissue ingrowth or that would stimulate scarring or epithelialization. Positioning the affixation devices may of itself induce some local tissue trauma that will stimulate reparative processes such as wound healing. This may take place by local irritation or by the presence of a material or a surface treatment on the device that stimulates collagen deposition or inflammation with subsequent scar tissue formation. The tensile strength produced by local reparative processes may, in certain embodiments, complement the tensile strength produced by the adherence of the fixation device in the soft tissue structures. In other embodiments, however, the fixation device itself, multiply or singly applied, will grasp the tissues with sufficient force and durability to hold the soft tissues in their preselected position. General principles of surgical judgment will guide the practitioner in determining the number of fixation devices to use for a particular application, and in determining their optimal insertion sites. In certain embodiments of the systems and methods of the present invention, templates may be provided that will guide the placement of the fixation devices into anatomically correct areas. Examples of templates will be illustrated below. Templates may further be used diagnostically, so that the positioning of a template within the vaginal vault in the office may replicate the tissue positioning that would be performed during a soft tissue reconstructive procedure. In the case of a cystocele or other pelvic floor abnormality, the positioning of the template may serve to reduce the defect to its anatomic position, and may thereby confirm the diagnosis of the underlying anatomic condition, and furthermore may justify operative intervention using the systems and methods disclosed herein. In other embodiments of these systems and methods, various diagnostic modalities may be used to identify the anatomic structures and tissues into which or through which a fixation device is to be inserted.

Representative diagnostic modalities include MRI, fluoroscopy, CT scan, conventional radiology, ultrasound, laparoscopy and endoscopy, although other modalities may be or may become apparent to practitioners of ordinary skill in the art. In certain embodiments of these systems and methods, furthermore, various modalities may be used to guide the placement of a fixation device through and into the appropriate anatomic structures. Representative modalities include MRI, fluoroscopy, CT scan, conventional radiology, ultrasound, laparoscopy and endoscopy, direct visualization (for example through a vaginal speculum or through an open laparotomy ~~incision~~incision), and intraoperative palpation, through a pre-formed surgical incision or through an incision created specifically to admit the surgeon's palpating finger or hand. Appropriate guiding modalities will be evident to surgical practitioners, based on the anatomic area under consideration.--

Please replace the paragraph beginning at page 20, line 15, with the following paragraph:

--Figure 5A shows an embodiment of a screw shaped as a coil 120 that can be used for tissue fixation according to these systems and methods. In Figure 5A, an insertion point 122 is adapted for penetrating the tissues to allow the flexible member 124 to be inserted therein. A screwing motion may be used to engage the anchoring tissues, or a motion similar to that used to insert a curved needle bearing a suture. In one embodiment, the insertion point 122 is directed distally through the anchoring tissue and then is redirected proximally, to be grasped by the operator. The curve 128 of the coil 120 is shaped to facilitate the encircling of the target tissue. Once the insertion point 122 has been redirected proximally and retrieved by the operator, it may be inserted into the latch 130 at the proximal end of the coil 120. As shown in Figure 5B, this

forms an outer ring 132 around an inner ring 134, with the target tissue 128 within these rings. To remove the device, the outer ring 132 can be disarticulated by removing the insertion point 122 from the latch 130, and then backing the coil out through the target tissue 138. Embodiments using the coil shape or modifications thereof may advantageously use flexible materials, whether metallic or polymeric. In certain embodiments, shape memory alloys may be used to achieve configurations such as those depicted in these figures, as will be readily apparent to artisans of ordinary skill in the art. The use of shape memory alloy (SMA) and the particular use of stress-induced martensite (SIM) alloy has been described in U.S. Patents No. ~~4,503,767~~4,505,767 and 5,597,378, the disclosures of which are incorporated herein by reference.--

Please replace the paragraph beginning at page 31, line 4, with the following paragraph:

--Figure 15 A-D show an alternate embodiment of a fixation device 450 adapted for positioning in a soft tissue, and further adapted for ready removal. In Figure 15A, a fixation device 450 is shown, comprising an expandable end 454 to the distal end 458 of which is affixed a pull wire 456 or a monofilament suture. The pull wire 456 passes through the hollow shaft 542 of the fixation device 450 to emerge through the proximal end 460. The proximal end 460 is adapted to be used with a bolster , as seen in Figure 15D. To insert the fixation device 450, it is placed within a delivery device that includes a distal needle 464. The ~~exoandable~~expandable end 454 is compressed so the device 450 can fit within the needle 464, as shown in Figure 15B. Figure 15C shows the needle 464 having penetrated an anchoring tissue 466. As the needle 464 is withdrawn, the expandable end 454 assumes its expanded contour. By further withdrawing the

needle and further applying traction to the ~~pullwire~~pull wire 456, the shape of the expandable end 454 can be further altered, as seen in Figure 15D. A proximal pull on the pull wire 456 will deform the expandable end 454 so that it assumes a mushroom shape 468 or some other shape intended to affix it in the tissues. The expandable end 454 is held in this mushroom shape 468 by continuous traction on the pull wire 456. To secure two tissues together, tension is applied to the pull wire 456 and the pull wire 456 is inserted through the bolster 462 and affixed thereto to provide constant tension. In order to remove the device, the pull wire 456 may be cut or disengaged, permitting the expandable end to revert from the mushroom shape 468 to its previous shape. Applying traction to the flexible expandable end 454 may permit its ready detachment from the tissues in which it has been embedded.--

Please replace the paragraph beginning at page 31, line 4, with the following paragraph:

--Figure 19A and B show yet another embodiment of a fixation device 850. In this embodiment, two pincers 852 are provided, attached to each other by a hinge and capable of rotating inwardly with the application of inward force. When inserted into target tissue, the insertion points 858 of the pincers 852 penetrate and engage the tissue. A lock ~~mchanism~~mechanism 856 located proximally can be activated after the pincers have adequately engaged the target tissue. Figure 19B shows the pincers 852 of the fixation device 850 in a closed position to engage the target tissue therebetween. In the depicted embodiment, a lock mechanism 855 may be activated to hold the pincers 852 in their closed position.--

Please replace the paragraph beginning at page 35, line 5, with the following paragraph:

--As has been mentioned previously, fixation devices according to the present invention advantageously are adapted for ready removal. The use of SMA and various SIM materials offers a mechanism by which easy insertion and ready removal may be achieved. Figure 20 A-D depict embodiments where a shape memory alloy may be used to alter the shape of the fixation devices after heating. Figure 20A shows a fixation device 880 according to the present invention ready for insertion. In the depicted embodiment, a horizontal bar 882 connects to a vertical arm 884 at each end. The dotted line 881 indicates the width of the device at the level of the horizontal bar 882. The vertical arms 884 are attached to the horizontal bar 882 at substantially right angles. Each vertical arm 884 is equipped with a penetrating end 886 dimensionally adapted for insertion through a first tissue into a second tissue. In an embodiment suitable for vaginal use, the entire vertical height of the fixation device 80 may be approximately 13 mm. Each vertical arm 884 is comprised of two segments, a proximal one about 8 mm in length and a distal one about 3 mm. in length. The length of the horizontal bar 882 may be about 10 mm. As shown in Figure 20B, with the application of heat, the proximal segment of the vertical arm 884 is bowed inward somewhat, while the distal segment of the vertical arm 884 bends on itself. Since the penetrating end 886 of each staple is optimally located in the target tissue, application of heat to the depicted device may affix it firmly within the target tissue. As indicated by the dotted line 881, the width at the level of the horizontal bar 882 does not change. Figure 20 C and D show modifications of the same structure. Figure 20C show a fixation device 880 adapted for insertion into intact tissues according to the systems and methods ~~doselosed~~disclosed herein. Once the insertion points 86 have entered the target tissue, then heat may be applied to the device 800. The application of heat may cause the fixation device 800 to bow in the distal part of its arms 884 and the distal part of the penetrating edge 888, as seen in Figure 20D. Figure 20D

shows the penetrating ends 886 of the vertical arms 884 to be nearly touching, and further shows a smoother configuration with fewer angulated edges than the device shown in Figure 20B.--

Please replace the paragraph beginning at page 39, line 16, with the following paragraph:

--Other gynecological and general surgical applications for these fixation devices may include rectocele and vaginal vault prolapse repair. Since the most proximal portion of the ATFP is located near the ischial spine, a procedure according to these systems and methods may provide apical support for vaginal vault prolapse. In addition, the fixation devices may be applied to the sacrospinous ~~ligament,whichcan~~ligament, which can also be palpated transvaginally, effecting vaginal vault suspension. For rectocele repair, fixation devices according to the invention may be applied to affix the inferior lateral sulci to the ATFP and/or the levator ani, depending upon the diagnosed anatomic defect.--

Please replace the paragraph beginning at page 42, line 21, with the following paragraph:

--An embodiment of an applicator for soft tissue fixation devices is depicted in Figure 26. The applicator 650 may be either ~~be~~ a disposable (multiple fire) or reusable instrument. In certain embodiments, the applicator 650 may be adapted for inserting serially a plurality of fixation devices. The fixation devices may be available in a cartridge or as a prepackaged unit for use with an applicator 650. In one embodiment, the applicator 650 may possess an articulating joint 652 and a rotating knob 654 to facilitate the insertion of the tip 653 of the device into small or angulated spaces. In one embodiment, the articulation joint 652 may permit

the tip 653 to be directed at a position perpendicular to the target tissue. The shaft 656 of the instrument may also rotate, directed by the rotating knob 654, providing another method to assure proper placement of the fixation device. In other embodiments, articulation may be performed with a lever or a wheel 658 near the proximal end 660 of the applicator 650. A lock mechanism (not shown) may be included to hold the instrument's articulable parts in their preselected position until altered by the operator. A handle 664 is provided to allow the operator to control the applicator 650, to position it in the anatomic region of interest and to direct the fixation devices into the tissue. After the applicator 650 has been positioned and has been inserted into an appropriate anatomic area to abut one of the tissues being approximated, the trigger 662 may be pulled to deploy an individual soft tissue fixation device. The next fixation device may automatically be brought into position for the subsequent firing. When the final fixation device has been placed, in one embodiment, the trigger 662 may no longer be capable of movement.--

In the claims:

Please amend claims 16, 19, 21, 26, 33, and 39 as follows:

16. (AMENDED) The system of claim 15, wherein the substance is selected from the group consisting of collagen, growth factor ~~or~~ and adhesion ligand.

19. (AMENDED) The system of claim 1, wherein the soft tissue fixation device is formed at least in part from a ~~bioabsorbable material~~bioabsorbable material.

21. (AMENDED) The system of claim 1, further comprising a remover to extricate the soft tissue fixation device from said at least two anatomic structures.

26. (AMENDED) The method of claim ~~19~~25, further comprising

providing a remover for atraumatically removing the soft tissue fixation device from the at least two anatomic structures,

examining a position of the soft tissue fixation device within the first and the second anatomic structure to determine whether said soft tissue fixation device is malpositioned, and

employing the remover to remove the soft tissue fixation device that is malpositioned.

33. (AMENDED) The method of claim 27, wherein the soft tissue structure comprises the rectum, wherein the first anatomic structure is a lateral vaginal sulcus and wherein the second anatomic structure comprises the ~~ATFP~~arcus tendineus fascia of the pelvis or the levator ani.

39. (AMENDED) A method of surgical paravaginal repair, comprising:

providing a soft tissue fixation device;

providing an insertion device adapted for inserting said soft tissue fixation device;

placing the soft tissue fixation device at least one of vaginally and laparoscopically through the stapling device; and

approximating the superior lateral sulci to the arcus tendineus fascia of the pelvis (ATFP) without exposing the ATFP through a surgical incision in a vaginal wall.